

CRACK IT

# CRACK IT Challenges Guide for Participants

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## CRACK IT programme overview

[CRACK IT](#) is an open innovation programme from the NC3Rs which supports the development of marketable products and improved business processes with 3Rs benefits.

The pharmaceutical, chemical and consumer products industries are increasingly seeking solutions from the academic and SME sectors for major challenges to their business. Often these challenges relate to the use of animals, for example the problem of predicting clinical efficacy and safety from non-clinical studies. We have responded to this with CRACK IT Challenges and CRACK IT Solutions which link big business, academia and the SME sector.

CRACK IT has two schemes:

- [CRACK IT Challenges](#) is a challenge-led, funding competition. Challenges are developed by Sponsors from industry, academia and the charitable sector in collaboration with the NC3Rs and put forward to all industries and academia for solving. Successful applicants receive funding from the NC3Rs and/or Sponsors along with in-kind support from the Sponsors (for example, data, compounds, equipment). Challenges are supported by the CRACK IT [Business Growth Scheme \(BGS\)](#), where all CRACK IT Challenge contractors, within 12 months of the end of their Challenge award, can apply for additional support to maximise their business strategy for near-market ready products and services. All awards made under the BGS constitute *de minimis* aid. Further information on eligibility criteria and the application process can be found in [Section 2](#).
- [CRACK IT Solutions](#) is a partnering hub for academics and SMEs to showcase their own ideas and technologies with 3Rs potential to the wider scientific community. Funding from the NC3Rs is available for further development, commercialisation and/or adoption.

# Section 1: CRACK IT Challenges

## 1.1 Overview

The CRACK IT Challenges competition consists of two challenge-led schemes:

- [CRACK IT Two Phase Challenges](#) require a significant amount of funding and may include research, development and validation of new technologies, prototypes and methods.
- [CRACK IT Single Phase Challenges](#) require less research and lower development costs compared to Two Phase Challenges and primarily focus on the validation of new technologies, prototypes and methods that are closer to market.

This document provides a comprehensive guide to participants in the CRACK IT Challenges competition whether they are from academia, the small and medium-sized company sector (SMEs), large industry or the charitable sector.

	Two Phase Challenges	Single Phase Challenges
Budget	From £100k - £1 million*	Up to £100k*
Duration	Up to three years	Up to one year

\*Inclusive of VAT/EU reverse charges

### Defining the Challenges

The Challenges are developed jointly by the NC3Rs and the Sponsors. CRACK IT Challenges are identified with Sponsors either through an open call or through office-led initiatives. Challenges can come from Sponsors from industry, academia or the charitable sector. Sponsors provide in-kind contributions (e.g. access to data, compounds, expertise etc.,) and/or co-funding to help solve the Challenge.

The [CRACK IT Advisory Panel](#) assess potential Challenges, taking into consideration external reviewer comments, and recommends to the NC3Rs which Challenges to run as competitions. An invitation to tender and brief for each Challenge is published on the [NC3Rs Innovation Platform](#) explaining the overall aims of the Challenge and the key deliverables.

The naming of the Sponsor(s) in the Challenge brief does not commit them legally to provide support; however, the expectation is that such support will be forthcoming for applications of very high quality. Sponsors should only participate with this intention in mind.

For further information on current Challenges, deadlines for submission and other important dates, please visit the [NC3Rs Innovation Platform](#).

### Building Teams to Solve the Challenges

The NC3Rs hosts a launch event to provide networking opportunities for potential applicants to meet new partners and the Sponsors so they can explore the scope of the Challenge and build the strongest possible team. Applicants are strongly encouraged to attend the launch event.

Sponsors of each Challenge hold a surgery at the launch event and frequently asked questions (FAQs) from the surgeries are published on the [NC3Rs Innovation Platform](#) after the event.

The NC3Rs facilitates interactions between applicants and Sponsors following the launch event.

Table 1: Challenges competition overview

Sponsor-led	<b>Defining the Challenges</b>	
	<p><a href="#">CRACK IT Challenges</a> are developed jointly by the NC3Rs and the Sponsors. The <a href="#">CRACK IT Advisory Panel</a> assess potential Challenges, and recommends to the NC3Rs which Challenges to run as competitions. An invitation to tender and brief for each Challenge is published on the <a href="#">NC3Rs Innovation Platform</a> explaining the overall aims of the Challenge and the key deliverables.</p>	
Applicant-led	<b>Building teams to solve the Challenge</b>	
	<p>The NC3Rs provides networking opportunities for potential applicants to identify new partners to build the strongest possible team, and to meet the Sponsors so they can explore the scope of the Challenge.</p>	
	<b>Application and review process</b>	
	<p><b>CRACK IT Two Phase Challenges:</b> This is a two phase application process:</p> <ul style="list-style-type: none"> <li>▪ <b>Phase 1</b> supports proof-of-concept studies for up to six months, with proposals assessed by a Review Panel.</li> <li>▪ At the end of Phase 1, a Challenge Panel recommends which project to support in <b>Phase 2</b> to address the full Challenge requirements, following a 'Dragons' Den' style interview. Entry into Phase 2 is dependent upon successful completion of Phase 1.</li> </ul>	<p><b>CRACK IT Single Phase Challenges:</b> This is a single phase application process:</p> <ul style="list-style-type: none"> <li>▪ Proposals for <b>Single Phase</b> Challenges describe plans for addressing the key deliverables detailed in the Challenge brief. This includes an assessment by a Review Panel.</li> <li>▪ The most promising proposals will be invited to a 'Dragons' Den' style interview by a Challenge Panel.</li> </ul>
Applicant & Sponsor-led	<b>Agreements and awards</b>	
	<p>Prior to award, the successful applicant's organisation signs an agreement with the NC3Rs. The NC3Rs will have an agreement with the Sponsor(s) and/or co-funder(s). An agreement is also recommended between the contractor (successful applicant) and the Sponsor(s).</p>	
	<b>Project management</b>	
	<p>Agreements are milestone-driven with regular Project Management Team meetings to ensure milestones are on schedule and to manage risks. <b>Two Phase Challenges:</b> the release of funds for <b>Phase 2</b> is dependent on the achievement of milestones.</p>	
<b>End of Challenge</b>		
<p><b>CRACK IT Advisory Panel meeting:</b> All CRACK IT Single and Phase 2 contractors will be invited to meet with the CRACK IT Advisory Panel no earlier than six (6) months before and no later than six (6) months after their contract with the NC3Rs expires.</p>		

## 1.2 Eligibility criteria

<b>Applicant eligibility</b>	<p>CRACK IT Challenges are run using the Small Business Research Initiative (SBRI) process which is supported by Innovate UK.</p> <p>The competition is open to:</p> <ul style="list-style-type: none"><li>▪ Any European Union (EU) body, public or private.</li><li>▪ Applications can be made from single organisations/investigators or from consortia.</li><li>▪ The lead applicant must be EU based.</li></ul> <p><b>Please note:</b> Phase 2 and Single Phase contracts are expected to be signed with commercial enterprises and not academic institutions.</p> <p>Applicants may already hold a grant or contract from the NC3Rs and other funding bodies for research related to the topic for which new funds are being sought and should provide details of all relevant research funding, including that from industry, in their application.</p>
<b>Sponsor eligibility</b>	<p>Challenges can come from Sponsors from industry, academia or the charitable sector.</p> <p>It is preferable but not essential that each Challenge has more than one Sponsor. Challenges should generally have broad relevance across the relevant industrial or academic sector.</p> <p>There is no restriction on where the Sponsor's contributory work is carried out. For practical reasons and for ease of project management, the UK/EU is preferred, but a case should be made for work outside the EU if this is critical to the success of the project.</p> <p>If the project is best served by one or more applicants working in the laboratories of the Sponsors outside the EU, this needs to be made clear in the Challenge brief. Prior settlement on the funding of such an arrangement is included in the agreement.</p>

### Independence

A typical project consists of at least two legal entities: one or more Sponsors and one contractor.

The legal entity receiving funding, for example an SME, must be independent from legal entities providing financial or in-kind support. Independence can be defined to mean that neither legal entity is under the direct or indirect control of the other. Control can take the form of directly or indirectly holding a majority of the nominal value of the issued share capital in the legal entity concerned, or a majority of the voting rights of the shareholders or associates of the entity, or directly or indirectly holding decision making powers in the entity, whether in fact or in law.

## 1.3 How to apply

Applicants to the CRACK IT Challenges competition are required to submit an application form which can be downloaded from the [NC3Rs Innovation Platform](#). [Section 1.4](#) provides guidance on completing the application form and should be read in conjunction with the Invitation to Tender prior to submission.

Lead applicants are expected, before submitting applications, to have discussed their proposals with their organisation or any other body whose co-operation will be required in the conduct of the project, including sub-contractors.

By submitting the application, applicants are confirming that the information given in the application is complete, that they are actively engaged in the project and responsible for its overall management, and agree to administer the award if made.

### **General Guidance for all applications**

- Applications for CRACK IT Challenges must be made using the application form and guidance available on the NC3Rs Innovation Platform. Completed applications must be sent by email to [crackitenquiries@nc3rs.org.uk](mailto:crackitenquiries@nc3rs.org.uk). All applications are treated in confidence.
- Application forms and attachments must be submitted as PDF files.
- Failure to complete mandatory fields on the application form and to submit all required attachment types with an application may result in the rejection/ return of the application.
- Where there is more than one organisation involved in the proposal, the application must be submitted by an agreed lead applicant and all other organisations listed as sub-contractors.
- The application form should be completed using a font size no smaller than 10pt (Arial) and text limits must not be exceeded.
- The use of acronyms should be kept to a minimum.
- If an applicant wishes to submit more than one application to the competition, they must contact the NC3Rs, via email [crackitenquiries@nc3rs.org.uk](mailto:crackitenquiries@nc3rs.org.uk) or call 020 7611 2233, before the competition deadline.
- Specific considerations to be taken into account for each Phase can be found in [Table 2](#).

### **Attachments**

Supporting information can be provided in the form of attachments as indicated within this guidance and the application form. Attachments must:

- Be submitted as separate PDF files.
- Be named appropriately and indicate the application form section number to which they refer e.g. Section 5 Additional Information/Diagrams.
- Not be added or pasted within the application form.
- Be completed using a font size no smaller than 10pt (Arial).

Only provide attachments as specified in the application form and in this guidance. Any additional materials or documentation submitted will not be considered and may result in your application being rejected/ returned.

Table 2: Phase specific considerations

<p><b>Single Phase</b></p>	<p><a href="#">Single Phase application forms</a> should be completed and submitted via email to <a href="mailto:crackitenquiries@nc3rs.org.uk">crackitenquiries@nc3rs.org.uk</a> before <b>12pm (noon) GMT, 13 November 2019</b>.</p> <p>The lead applicant is expected to be a commercial entity and not an academic institution.</p> <p>The latest date for commencing work on the Single Phase award is 2 March 2020, eight (8) weeks after the Dragons' Den meeting. Incorrect start dates may result in applications being rejected/ returned.</p>
<p><b>Phase 1</b></p>	<p><a href="#">Phase 1 application forms</a> should be completed and submitted via email to <a href="mailto:crackitenquiries@nc3rs.org.uk">crackitenquiries@nc3rs.org.uk</a>. The deadline for application submission is <b>12pm (noon) GMT, 6 November 2019</b>.</p> <p>Applicants may be able to demonstrate that they have already proven the feasibility of their idea in meeting Phase 1 deliverables. In this case, applicants should nevertheless apply for Phase 1, setting out:</p> <ul style="list-style-type: none"> <li>▪ How they have already achieved the Phase 1 deliverables</li> <li>▪ Plans for tackling the Challenge as a whole, but without requesting funding for Phase 1</li> </ul> <p>Applications are considered by the Review Panel, with successful applicants invited to participate in the subsequent Phase 2 competition. Applicants must be able to start the Phase 1 project no later than 6 January 2020. Incorrect start dates may result in applications being rejected/ returned.</p>
<p><b>End of Phase 1: Proof-of-concept report</b></p>	<p>All awardees of Phase 1 funding are required to submit a proof-of-concept report and final expenditure statement (FES), regardless of whether they wish to continue to Phase 2, describing:</p> <ul style="list-style-type: none"> <li>▪ How they have met the Phase 1 deliverables</li> <li>▪ Detailed plans for addressing the Phase 2 deliverables set out in the Challenge brief</li> </ul> <p>Failure to provide a proof-of-concept report, demonstrating the work undertaken, may result in the Phase 1 funding being rescinded.</p> <p>The report template and FES will be sent to all Phase 1 awardees at least six (6) weeks before the Phase 2 application deadline as part of the Phase 2 application pack.</p>

## Phase 2

A Phase 2 application pack will be sent to all Phase 1 awardees at least six (6) weeks before the Phase 2 application deadline. The Phase 2 application pack includes:

- Phase 2 application form
- Phase 1 award letter containing Review Panel feedback. Any feedback provided by the Review Panel should be addressed in the application for Phase 2.
- Challenge Panel guidance for applicants
- PowerPoint presentation template
- Proof-of-concept report template
- Final Expenditure Statement (FES) template
- Challenge brief

[Phase 2 application forms](#) should be completed and submitted via email to [crackitenquiries@nc3rs.org.uk](mailto:crackitenquiries@nc3rs.org.uk) before **12pm (noon) BST, 17 June 2020**.

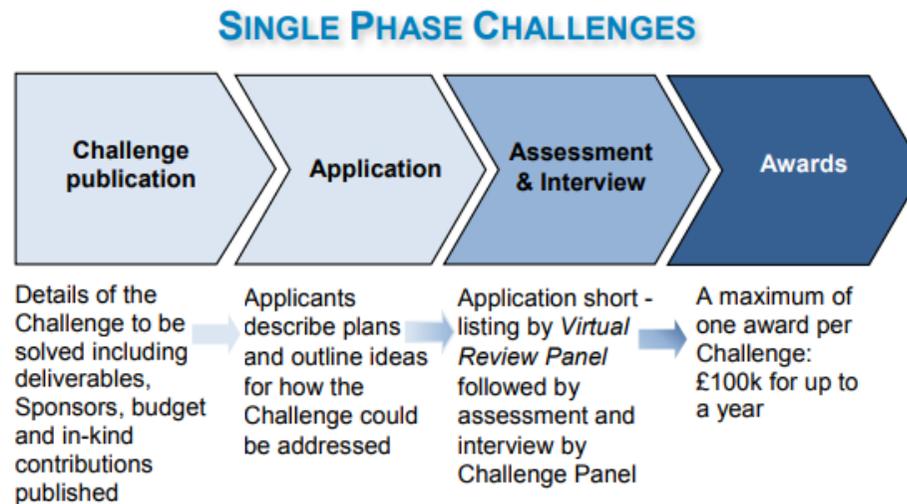
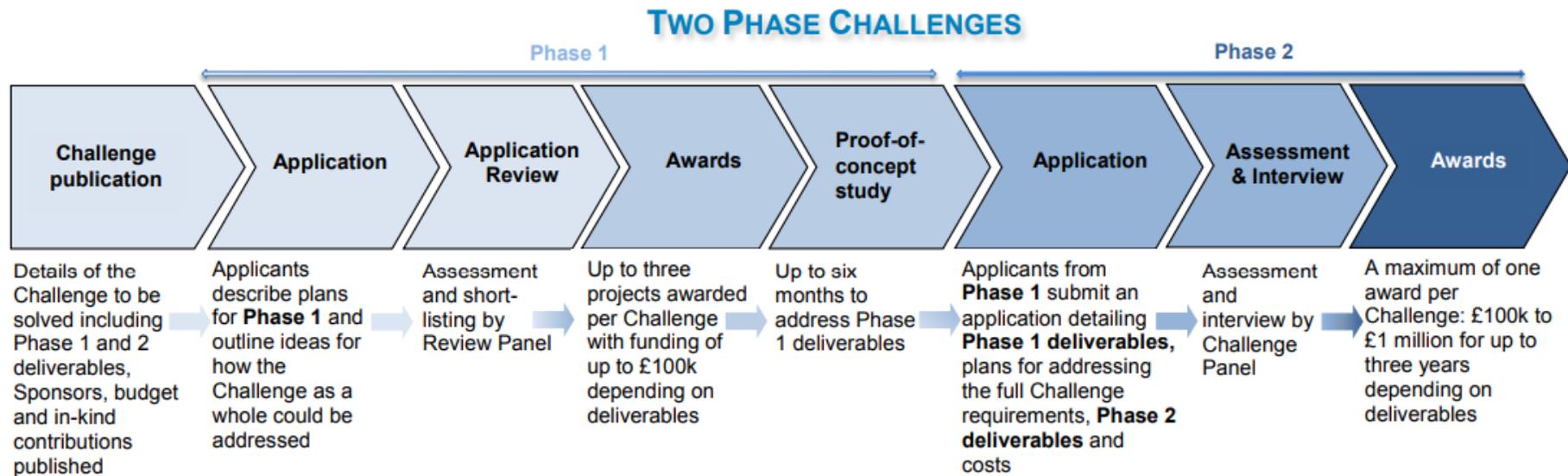
The lead applicant for Phase 2 is expected to be a commercial entity and not an academic institution.

Successful Phase 2 applicants must start the project within six (6) months of the confirmation of the award. Incorrect start dates may result in applications being rejected / returned.

Questions about the application process should be addressed directly to the NC3Rs via email [crackitenquiries@nc3rs.org.uk](mailto:crackitenquiries@nc3rs.org.uk) or phone +44 (0)20 7611 2233.

The NC3Rs reserves the right to amend the application process.

Summary of the application process \*



\*The NC3Rs reserves the right to amend the application process.

## 1.4 CRACK IT Challenges application form

This section contains guidance on how to complete the application form. Sub-sections are numbered as they appear in the application form.

### 1. Application

**Project Title:** Please provide your own title for the project. This should be both clearly descriptive and concise. It should contain keywords relevant to the project.

**Project Duration:** As specified in the Challenge brief.

**Total Cost (£s):** Proposed projects can request up to the maximum total cost, inclusive of VAT/EU reverse charges, which is specified in the Challenge brief. Requests for more than this sum will be rejected.

For applications from organisations based outside of the United Kingdom, please note that a European Union (EU) reverse charge of VAT will be applied to your award. This will be charged at 20% and will need to be taken into consideration when costing your application, as the maximum amount that will be paid out inclusive of VAT and EU Reverse Charges will not exceed the total amount offered for the Challenge.

**Challenge Number:** Please select the number of the Challenge for which you wish to apply from the drop-down menu.

**Proposed Start Date:** Please refer to the specific guidance provided in [Table 2](#).

### 2. Details of Lead Applicant Organisation

Please include the name of the company/ organisation of the lead applicant, and other details as requested on the application form.

- If the **Phase 1** application is being made from an academic institution, please select 'Other' from the Business Sector drop down menu.
- Applications to **Phase 2** and **Single Phase** competitions are expected to be made from a commercial entity and not an academic institution.

### 3. Contact Details

Please provide the lead applicant's name, company/organisation name, position etc.

### 4. Abstract for Publication

Please describe the proposed project in simple terms suitable for a lay audience.

**Please note** - the NC3Rs publishes abstracts from its funded contracts on the NC3Rs website to demonstrate the potential impact of its funded research. Applicants are responsible for ensuring that any confidential information, or information that might be considered controversial or sensitive, is not included within the abstract.

### 5. Description of Proposed Idea/ technology

Describe clearly how your proposed idea or technology will deliver the outcomes as outlined in the Challenge brief, avoiding the use of unnecessary technical jargon.

- For **Phase 1** (section 5a) and Single Phase applications, please provide a general overview on your approach to addressing the Challenge as a whole;

- For **Phase 1**, please also provide your approach to addressing Phase 1 deliverables (section 5b);
- **Phase 2** applications should take account of what has been achieved in Phase 1.

**Associated attachment (optional): Additional pictures or diagrams**

Phase 1: maximum two sides of A4 for each sub-section, 5a and 5b.

Phase 2: maximum two sides of A4.

## 6. Scientific/Technical Project Summary

Please provide a structured summary of the scientific and technical basis of the project. This should detail the approach to be taken, including what is innovative, and the key deliverables. Include details of the research and development that will be done in order to demonstrate the scientific merit of the project. Describe the key scientific and technical challenges of the project and how they will be overcome, including consideration of alternative and risk management strategies. In this section refer, where necessary, to the resources required as in-kind contribution from the Sponsor(s).

**Please note:** If a proposal includes animal work, the [Justification of Animal Use/Experimental Design form](#), must be completed and included as part of the application. Further guidance can be found in [Section 1.4.1](#)

**Associated attachment (mandatory for Phase 2):**

End of Phase 1 proof-of-concept report for which a template will be provided.

## 7. Current State of the Art and Intellectual Property (IP)

Describe the current state of the art and any competing or alternative strategies. Explain the benefits of your proposed approach to the Challenge. Include details of any other existing IP and its significance to your freedom to operate. Include details of your own background IP and any restrictions this may impose on the dissemination and exploitation of the project findings.

Ownership and exploitation of foreground IP should be included in **section 8** of the application form.

## 8. Project Plan and Methodology

The project plan should identify the major packages of work, with well-defined milestones and key deliverables. The key scientific lead for each milestone should be listed.

Please include plans for commercialisation of the results of the project.

- **Project Management:** Identify the project management processes that you will use to ensure that milestones are achieved in a timely manner. In addition, please provide details of identified risks and mitigation strategies.
- **Proposed Arrangements for IP:** Please provide an indication of how any IP, which might arise during the project, would be handled i.e., the proposed arrangements for ownership, exploitation and dissemination.

For **Phase 2** applications, milestones must be at six (6) monthly intervals for the duration of the project. Include in the resource requirements section, details of the in-kind contributions that will be needed from the Sponsor(s). The emphasis throughout should be on practicality – we are seeking evidence that the technology works, can be made into a viable solution to the Challenge and can achieve the proposed benefits.

**Associated attachment (mandatory for all applications)**

Additional milestones/Gantt chart (maximum two sides of A4).

## 9. Scientific/Technical Team and Expertise

Provide a detailed description of the skills, expertise and track record of the team, including those of any sub-contractors. Indicate the relevant knowledge and skills of each member and the proportion of their time that will be spent on the project. Relevant commercial and management expertise should also be included.

### **Associated attachment (mandatory for all applications):**

CVs of **up to five** principal team members may be combined and included as a separate attachment (maximum of one side of A4 per team member)

## 10. Application Finances

CRACK IT contracts are non-Full Economic Costing (FEC) and as such, applicants can apply for **100% directly incurred** and **indirect costs**. Please provide a summary of the overall costs for the whole project, inclusive of VAT/EU Reverse Charges, as appropriate<sup>1</sup>.

For applications from organisations based outside of the United Kingdom, please note that a European Union (EU) reverse charge of VAT will be applied to your award. This will be charged at 20% and will need to be taken into consideration when costing your application, as the maximum amount that will be paid out inclusive of VAT and EU Reverse Charges will not exceed the total amount offered for the Challenge.

In addition, please detail the model used to calculate costs and provide justification for (i) the model used and (ii) the resources required to undertake the proposed project.

Please note: Review and Challenge Panels are required to judge requested resources in terms of value for money i.e., does the proposed cost for effort and deliverables reflect a fair market price. The costs should cover the following, as applicable:

### **Direct Costs**

These are costs that are specific to the project, including:

- Labour costs for all those contributing to the project broken down by individual
- Material Costs (including consumables specific to the project)
- Capital Equipment Costs
- Animal costs
- Travel and subsistence
- Other costs specifically attributed to the project (e.g. costs associated with protection of IP)

### **Indirect Costs**

Indirect costs should be charged in proportion to the amount of effort deployed on the project.

Applicants should calculate them, using their own cost rates, and may include:

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<sup>1</sup> It is the responsibility of the lead applicant to determine whether VAT/EU RC should be paid; if VAT/EU RC should be paid, the total amount requested, including VAT/EU RC, should not exceed that offered for the Challenge.

- General office and basic laboratory consumables
- Library services/learning resources
- Administrative support
- Finance, personnel, public relations and departmental services
- Central and distributed computing
- Cost of capital employed
- Overheads
- Publications and Open Access publishing (for non-academic and non-UK based applicants)

Itemisation of costs and methods of calculation may be requested to support the application at a later date.

Please note - The NC3Rs will not cover applicants travel costs to the Challenge Panel.

**Associated attachment (mandatory for all applications):**

If the proposal involves sub-contractors, applicants must provide a breakdown of the costs for each contributing organisation. This should be in the same table format as in Section 10 of the application form and combined in one PDF document.

**Payment Schedule:** For **Phase 1** and **Single Phase**, costs will be paid on receipt of the signed contractor agreement. **Phase 2** funding is released quarterly and is dependent on the achievement of milestones.

**Funding from other public and private bodies:** Please provide details of other funding - both public and private, for related work, including the source and the amount.

**IMPORTANT:** Please note, for the first (Q1) payment of Phase 2, the amount requested must not exceed 15% (inclusive of VAT) of the total award.

#### 11. Plans for dissemination and commercialisation of Challenge product

The Challenge brief outlines that the CRACK IT Challenges competition is designed to support the development of new 3Rs technologies and approaches, which will improve business processes and/or lead to new marketable products. Please include a plan for commercialisation and dissemination of the Challenge product.

#### 12. 3Rs Impact Assessment

The Challenge brief outlines the potential 3Rs benefits arising from the successful completion of the project. Please provide your own assessment of the 3Rs impact of the work, including quantitative estimates of the numbers of animals affected wherever possible.

#### 13. Declaration

The lead applicant is expected to have discussed the application within their own organisation and with any other body whose co-operation will be required to deliver the project. The lead applicant will need to obtain consent from an authorised officer or appropriate signatory who will sign the agreement if successful. The agreement is a legally binding document and subject to the outcome of this competition. By submitting the application, you are confirming that the information given, in the application, is complete and that you are actively engaged in the project and responsible for its overall management and agree to administer the award if made. You are also confirming that you have read and understood the relevant explanatory materials including the Invitation to Tender and this Guide for Participants.

**Please note:** The application cannot be accepted without the Declaration section being completed.

Table 3: Summary of attachments

Application form section	Attachment name	Page limit (sides of A4)	Application stage applicable*
Section 5(a)	Additional information/diagrams	2	P1, P2, SP
Section 5(b)	Additional information/diagrams	2	P1 only
Section 6	End of Phase 1 proof-of-concept report	Template provided	P2 only
Section 8	Additional milestones/ Gantt chart	2	P1, P2, SP
Section 9	CV	1 per team member (5 in total)	P1, P2, SP
Section 10	Subcontractor costings	1 table per subcontractor	P1, P2, SP
Projects involving animal use	See section <a href="#">1.4.1</a> and <a href="#">1.4.2</a> for guidance on additional information required		P1, P2, SP as required

\*P1 = Phase 1, P2 = Phase 2, SP = Single Phase

### 1.4.1 Animal use and experimental design

Where a proposal includes animal work, the [Justification of Animal Use/Experimental Design form](#), must be completed and included as part of the application. Guidance on completing this form can be found within this section.

Applicants are expected to have developed their application in accordance with the cross funder guidance for the use of animals in research [Responsibility in the Use of Animals in Bioscience Research](#) and, in the case of use of non-human primates, the [NC3Rs Guidelines: Primate Accommodation, Care and Use](#). Compliance with the principles within these documents is a condition of receiving funds from the NC3Rs.

Experiments using animals funded by the NC3Rs must also comply with the Animals (Scientific Procedures) Act 1986, amended 2012 ([ASPA](#)) and any further embodiments, in:

- using the simplest possible, or least sentient, species of animal appropriate
- ensuring that pain and distress are avoided wherever possible
- employing an appropriate design and using the minimum number of animals consistent with ensuring that scientific objectives will be met

Advice on opportunities and techniques for implementing these 3Rs principles can be found on the [NC3Rs](#) website.

Researchers using animals are strongly advised to read this guidance carefully before preparing an application to ensure all the relevant information required is included in their

application. In particular, applicants should ensure their application clearly sets out and justifies the following:

- research objectives and how the knowledge generated will advance the field
- the need to use animals and the lack of realistic alternatives
- choice of species of animals to be used
- type of animal(s) for example, strain, pathogen free, genetically modified or mutant
- planned experimental design and its justification
- number of animals and frequency of measurements/interventions to be used
- primary outcomes to be assessed
- planned statistical analyses

### **Experimental design, avoidance of bias and statistical considerations**

There are a wide range of designs and approaches to animal experimentation that are appropriate depending on the objectives of the application. In all cases, the NC3Rs expects that researchers provide well justified information in their applications concerning the experimental design and its suitability to answering the research questions posed. Applicants should therefore provide adequate justification for their choice of design and numbers of animals and interventions. It is important that adequate information is also given concerning methodological issues including (but not restricted to) the bullet points below.

- The avoidance of bias (for example blinding of observers assessing outcomes to the group allocation in a randomised design);
- How randomisation will be carried out (if used) or why it is not appropriate if it will not be used;
- A clear definition of the experimental unit in the analysis and the implications thereof (that is there is a difference between N samples from one animal, as distinct from one sample from each of N animals/or combining samples from multiple animals);
- A principled justification of the adequacy of the number of animals to be included so as to be able to minimise the likelihood of spurious results due to the play of chance alone.
- Where animals are used in multiple types of experimental approach within a single application (e.g. for tissue supply, pilot experiments or more defined pre-clinical studies), exemplars for these types of experiment should be provided.
- The number of different time points at which measurements will be made on each animal.
- A description of the statistical analysis methods that will be used, explaining how they relate to the experimental design and showing that they are appropriate for the types of data that will be collected.

- An indication of the number of independent replications of each experiment to be performed with the objective of minimising the likelihood of spurious non-replicable results.

The **NC3Rs Experimental Design Assistant** (EDA, <https://eda.nc3rs.org.uk>) captures methodological details about the experimental plan in the form of a diagram, and provides tailored guidance and feedback on the design. It can then generate a PDF report which provides a transparent description of the experimental design in a standardised format.

### Guidance on completing the '[Justification of animal use/ experimental design form](#)'

Information must be provided for all applications involving animals (including where the only procedure is Schedule 1 killing), regardless of whether or not the animal costs are requested as part of the application.

- Please provide details of any procedures categorised as moderate or severe, including how the procedure is undertaken, adverse effects experienced by the animals, and measures taken to minimise any pain, suffering, distress or lasting harm. (Address this point in response to **question five** on the form).
- If use of **non-human primates, cats, dogs, pigs or equines** will be involved in the addressing the Challenge, applicants must also complete [Annex 1](#). All applications which involve the use of these higher species are reviewed by the NC3Rs Office to ensure the usage is fully justified and that the welfare and husbandry standards are optimal.
- Sound scientific reasons for the use of animals and an explanation of why there are no realistic alternatives must be given, along with an explanation of how the choice of species complies with ASPA. (Address this point in response to **question eight** on the form).
- The **experimental design** should be outlined, including a justification of the total numbers of animals to be used and, where appropriate, the frequency of measurements/interventions required on each animal. Planned procedures to minimise experimental bias (for example, randomisation protocols, blinding) should be outlined or an explanation included as to why such procedures are not appropriate. Each experiment does not need to be described in detail, but sufficient information must be included so that reviewers are readily able to understand the experimental plan. (Address this point in response to **question 10** on the form).
  - Researchers must provide a properly constructed justification of how the numbers of animals to be used were determined. In general, it would be expected that professional statistical advice is sought in compiling this answer.
  - In many instances this answer will include statistical power calculations<sup>2</sup> based on justifiable and explicit assumptions about the anticipated size of the experimental effects. If statistical power calculations are not given, applicants should provide a principled explanation of the choice of numbers. In general, explanations based solely in terms of 'usual practice' will not be considered adequate. An overview of the planned statistical analyses and their relation to the choice of sample size should be included.

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<sup>2</sup> Power calculations can be used to calculate the minimum sample size required so that one can be reasonably likely to detect an effect of a given size, or to calculate the minimum effect size that is likely to be detected in a study using a given sample size.

- Where experiments involve genetically altered animals, examples of the breeding strategies should be included to support the total number of animals requested. Please provide information on resources requested for breeding, maintaining and using the chosen number of animals; the scientific and statistical justification of how the chosen number of animals was arrived at.

### **Additional Information**

- The costs of both the animals themselves and their maintenance may be requested and should be listed in the 'Application Finances' section of the application form under Directly Incurred costs.
- Applicants contemplating the use of animals purchased from commercial suppliers should, wherever possible, use UK suppliers, to minimise the risk of suffering during transport. For cats, dogs and primates, Home Office-approved suppliers must be used. Applicants planning research using rhesus macaques should obtain animals from the Centre for Macaques.

### **Ethical and welfare standards and review**

Applicants must ensure that best practice in relation to animal husbandry and welfare is followed. Where the work proposed is not covered by an existing Project Licence under ASPA, applicants should put their applications to the local Animal Welfare and Ethical Review Body (AWERB) for review prior to submission and ensure that ethical or welfare issues raised are addressed.

If applicants are proposing to undertake any animal experiments as part of collaborative programmes outside the UK, these experiments must be conducted in a way that conforms to the legal, ethical and normal practices in that country, as well as conforming to the standards (including animal welfare) required in the UK. Where the standards are different, the more rigorous will apply. See p14 [Responsibility in the Use of Animals in Bioscience Research](#).

### **Home Office licences**

It is the responsibility of all applicants to ensure that the appropriate Home Office licences are obtained. This will include the requirement that the research applications are approved by the local AWERB. Home Office licences (or amendments to existing licences) do not have to be obtained before the application is submitted to the NC3Rs, but if a contract is awarded, contractors (successful applicants) must have the necessary licences in place before any animal experimentation begins.

### **Mouse strains**

The NC3Rs encourages the archiving and sharing of genetically altered mouse strains as a means of both reducing and refining animal use<sup>3</sup>. The MRC supports a central repository of mouse strains, the Mouse Frozen Embryo and Sperm Archive (FESA) at MRC Harwell. FESA aims to ensure that valuable mouse strains are safeguarded, that the need to maintain colonies of live mice for long periods of time is reduced, and that the significant investment in engineering strains is capitalised upon fully.

Where there may be a need for the repeated creation of pre-existing genetically modified mouse strains, this must be fully justified. Applicants planning to produce genetically modified mouse strain(s) should investigate whether suitable strains are available via FESA or elsewhere

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<sup>3</sup> See ["Sharing and archiving of genetically altered mice: Opportunities for reduction and refinement"](#).

before requesting resources for creating new strains. Applicants planning on creating new genetically altered mouse strains as part of their work should actively consider archiving and sharing these strains via FESA. When archiving and sharing of genetically modified mice is not possible, please clearly state in your application the reasons for this.

Contact: FESA [fesa@har.mrc.ac.uk](mailto:fesa@har.mrc.ac.uk)

#### 1.4.2 Use of animals outside of the UK

If a project involves the use of animals outside of the UK, a dated and signed letter of support from all applicants stating the below must be included as a separate PDF attachment to the application:

- They will adhere to all relevant national and local regulatory systems in the UK and overseas.
- They will follow the guidelines laid out in the Responsibility in the Use of Animals in Bioscience Research and ensure that work is carried out to UK standards.
- Before initiation of the proposed research work, appropriate approvals from Institutional and/or central animal ethics committees will be obtained for experimental protocols to be adopted in their projects. Successful proposals may be expected to provide copies of these permissions before funding is released.
- Details on where the animal research will take place (UK or overseas) and through which funder the resources are being sought.

If the research involves the use of rodents outside of the UK, please also complete the [additional questions on the use of rodents overseas form](#), and attach in PDF format with your application.

Additional guidance on conducting and reporting animal research can be found on the NC3Rs' [Peer review and advice service hub](#).

## 1.5 Assessment procedures

### 1.5.1 The Review Panel

The evaluation of applications for **Phase 1** and **Single Phase** is undertaken by a Review Panel and a Review Panel via teleconference respectively.

The **Phase 1** Review Panel:

- Assesses Phase 1 applications and recommends up to three of the most promising applications to carry out the Phase 1 proof-of-concept stage for Two Phase Challenges.
- Phase 1 applicants will receive feedback from the Review Panel and awards will be made to the successful applicants' organisations subject to signing a non-negotiable [Phase 1 contractor agreement](#) with the NC3Rs.

The **Single Phase** Review Panel:

- Assesses submitted applications and shortlists the most promising proposals to invite to the Challenge Panel.
- Shortlisted applicants receive feedback from the Review Panel which should be addressed in their presentation at the Challenge Panel.

The lead applicants are informed by email of the decision of the Review Panel approximately one week after the Panel meeting. The Review Panel's decision is final and not open to appeal.

The Review Panel and Chair are appointed for each Challenge by the NC3Rs and consists of experts from academia and industry with the appropriate business development experience. Each Panel also includes a representative(s) from the Challenge Sponsors. Members of the Review Panels may also participate in the Challenge Panels.

Membership of the Review Panels is published on the [NC3Rs Innovation Platform](#).

Table 4: Review Panel scoring criteria

Phase 1 Review Panel	Single Phase Review Panel
<ul style="list-style-type: none"><li>▪ Quality of the science and technological innovation</li><li>▪ How the proposal will meet Phase 1 deliverables</li><li>▪ Expertise and track record of the team</li><li>▪ Value for money</li><li>▪ Plans for solving the Challenge as a whole</li><li>▪ Interpretation of the 3Rs impact</li><li>▪ Plans for dissemination and commercialisation of Challenge Product</li><li>▪ Sponsor interaction and collaborative potential</li></ul>	<ul style="list-style-type: none"><li>▪ Quality of the science and technological innovation</li><li>▪ How the proposal will meet the key deliverables set out in the Challenge brief</li><li>▪ Expertise and track record of the team</li><li>▪ Value for money</li><li>▪ Interpretation of the 3Rs impact</li><li>▪ Plans for dissemination and commercialisation of Challenge Product</li><li>▪ Sponsor interaction and collaborative potential</li></ul>

## 1.5.2 The Challenge Panel

The evaluation of **Phase 2** and **shortlisted Single Phase applications** is undertaken by their respective Challenge Panels, run in a 'Dragons' Den' style.

The **Phase 2** Challenge Panel:

- Discusses the results of the Phase 1 stage, judges the progress against the Phase 1 key deliverables, assesses and questions applicants on their proposals to:
  - Solve Phase 2 deliverables as outlined in the Challenge Brief
  - Address the feedback provided by the Review Panel
- The Challenge Panel recommends up to one Phase 2 award per Challenge with funding of up to £1 million for up to three years, depending on the Challenge.

The **Single Phase** Challenge Panel:

- Assesses and questions shortlisted applicants on their proposals to address:
  - The key deliverables as outlined in the Challenge brief
  - The feedback provided by the Review Panel
- The Challenge Panel recommends up to one Single Phase award per Challenge with funding of up to £100k for up to one year.

Presentations to the Challenge Panel are made by **no more than two speakers**, one of whom must be the lead applicant. A presentation template and guidance will be provided in advance of the deadline. A maximum of six additional team members are welcome to also attend the interview to answer the Panel's questions.

Up to one award will be made per Challenge. If none of the applications provide adequate evidence of their ability to meet the criteria and deliver the Challenge, then no award will be made. The lead applicant will be informed by email of the decision of the Challenge Panel approximately one week after the presentation. The Challenge Panel's decision is final and is not open to appeal.

The NC3Rs will not cover costs associated with travel to the Challenge Panel interviews.

The Challenge Panel and Chair are appointed for each Challenge by the NC3Rs and includes the Sponsors and independent experts. The members of the Challenge Panel who represent the Sponsors should consult within their companies to ascertain their level of commitment and come to the meeting with delegated authority to make decisions on funding or in-kind contributions. In the event that Challenge Sponsors are unable to agree on which applications to support, the NC3Rs may decide that it is more appropriate for each Sponsor to fund its preferred application directly without the financial involvement of the NC3Rs. Such decisions are agreed on a case-by-case basis between the Sponsors and the NC3Rs.

Membership of the Challenge Panels is published on the [NC3Rs Innovation Platform](#).

Table 5: Challenge Panel scoring criteria

Two Phase Challenge Panel	Single Phase Challenge Panel
<ul style="list-style-type: none"> <li>▪ Completion of Phase 1 deliverables and response to Review Panel feedback for Phase 1</li> <li>▪ Ability to deliver what is stated in the Phase 2 application, including deliverables as outlined in the Challenge brief</li> <li>▪ Originality and level of technological innovation of the proposal</li> <li>▪ Motivation to drive and manage the project, risk mitigation and delivery of milestones</li> <li>▪ Strength of the team</li> <li>▪ Interpretation of the 3Rs impact</li> <li>▪ Plans for dissemination and commercialisation of Challenge Product</li> <li>▪ Sponsor interaction and collaborative potential</li> <li>▪ Value for money</li> </ul>	<ul style="list-style-type: none"> <li>▪ Quality of the Science and Technological innovation</li> <li>▪ How the proposals will meet the key deliverables as outlined in the Challenge brief</li> <li>▪ Expertise and track record of the team</li> <li>▪ Interpretation of the 3Rs impact</li> <li>▪ Plans for dissemination and commercialisation of Challenge Product</li> <li>▪ Sponsor interaction and collaborative potential</li> <li>▪ Value for money</li> </ul>

**Panel Terms of Appointment, Code of Conduct and Conflicts of Interest**

Members of the Review and Challenge Panels are expected to abide by the principles set out in the [Code of practice for members of Council and MRC boards](#). On appointment to the Panel, members are required to complete a declaration of interests form and sign a confidentiality agreement. A full list of Panel members, their affiliated organisations and completed declarations of interest forms are published on the [NC3Rs Innovation Platform](#).

**1.6 Award process**

Awards are made to the successful applicant’s organisation, who then administers the award, subject to them signing a non-negotiable agreement with the NC3Rs ([Phase 1](#), [Phase 2](#) and [Single Phase](#) contractor agreements).

For successful applications, involving more than one organisation, the lead applicant (contractor) must agree to manage the award from the NC3Rs on behalf of the others (the sub-contractors). Sub-contractors negotiate their agreements with the contractor directly.

Furthermore, should they be successful, applicants should be able to demonstrate that they have a team in place ready to start working on the project on receipt of the agreement.

Contracts are expected to be finalised and signed within **two weeks** of receipt.

The NC3Rs leads the awards’ announcements via the [NC3Rs Innovation Platform](#). Award holders may be required to participate in media-related activities regarding the announcements.

### 1.6.1 Phase 1 awards

Awards made following the Review Panel are subject to the terms outlined in the [Phase 1 contractor agreement](#), including the deadline for Phase 2 applications. Where in-kind contributions are required, it may be necessary for the applicant and Sponsor to sign an agreement before starting the proof-of-concept study.

Phase 1 awardees are expected to start work on receipt of the agreement and no later than **6 January 2020** as the deadline for Phase 2 applications, 17 June 2020, will not be extended.

Full payment of the total amount specified in the agreed payment proposal will be released on receipt of a signed copy of the contract.

### 1.6.2 Phase 2 and Single Phase awards

**Phase 2** and **Single Phase** awards are made to the successful applicant's organisation subject to them signing a non-negotiable agreement with the NC3Rs. The NC3Rs also has an agreement with the Challenge Sponsor(s) and/or co-funder(s). A further agreement between the successful applicant's organisation and the Sponsor is also recommended.

**Please note:** Phase 2 and Single Phase agreements are expected to be signed with commercial entities and not academic institutions.

- **Phase 2** work should commence promptly and within six (6) months of the confirmation of the award from the NC3Rs. Failure to comply will result in the award being terminated.

To allow for the purchase of equipment etc., and to ensure rapid commencement of work, the first payment can typically be 10-15% of the total award amount. Thereafter funding is released quarterly and is dependent upon the achievement of milestones, as defined in the agreement between the successful applicant's organisation and the NC3Rs. Payments will begin on receipt of a signed copy of the contract.

- **Single Phase** work should commence promptly and within eight (8) weeks of the confirmation of the award from the NC3Rs and no later than **2 March 2020**. Failure to comply will result in the award being terminated. To ensure rapid commencement of the work, all funding will be provided upfront. Full payment of the total amount specified in the agreed payment proposal will be released on receipt of a signed copy of the contract.

#### Important information

The Terms and Conditions for all CRACK IT awards are set out in the agreement between the NC3Rs and the successful applicant (Contractor Agreement) and the agreement between the NC3Rs and the Sponsor(s) and/or co-funder(s).

Contractor agreements are available to download from the [NC3Rs Innovation Platform](#). Applicants are strongly advised to read the agreements prior to applying. The NC3Rs will have an agreement with the Sponsors and/or co-funder(s) and an agreement is also recommended between the successful applicant and the Sponsor(s).

Agreements:

- Agreements between the NC3Rs and the Challenge winners take the form of standard contract research agreements from the NC3Rs.
- These agreements are intended to protect and benefit both the NC3Rs and the Challenge winners to ensure the effective delivery of the research.
- Agreements are standard across all Challenges and they are non-negotiable. The NC3Rs will not amend these agreements.

- Agreements between the Sponsor and the Challenge winners should be made at their discretion. This can range from a Confidential Disclosure Agreement (CDA) or a Material Transfer Agreement (MTA) to a full contract.

## Sponsors

Sponsorship normally takes the form of in-kind contributions. Although no formal estimation of the value of the in-kind contribution or auditing of the work done is undertaken, the NC3Rs expects Sponsors to act in good faith in providing an in-kind contribution that adds significant value to the financial contribution of the NC3Rs and is complementary to the research undertaken by the academic/SME partner(s).

A list of the in-kind contributions is required for the Challenge brief. These might include data, data processing, clinical materials, human and animal cells and tissues, access to equipment, complementary in-house experiments, hosting of investigators, etc.

- Sponsors do not normally provide in-kind contributions to applicants awarded **Phase 1** funding. In some circumstances, however, depending on the Challenge, in-kind contributions may be necessary. In these cases, an agreement is recommended between the Sponsor(s) and the applicant.
- For **Phase 2** and **Single Phase** awards the list of in-kind contributions forms part of the agreement between the NC3Rs and the Sponsor(s).

If the in-kind contribution from the Sponsors involves the use of animals, the research must conform to the standards required by UK legislation and adhere to the [Guidance on Responsibility in the Use of Animals in Bioscience Research](#), even if this work is conducted outside the UK.

## 1.7 Post award information

### 1.7.1 Intellectual property

Intellectual property (IP) developed within the project is the property of the contractor (Challenge winner) and its sub-contractors, as described in the agreement between the NC3Rs and the contractor. One recipient of NC3Rs funding should be nominated as the IP manager for the project. The NC3Rs does not provide a model agreement but suggests as a default that IP arising from the research should be jointly owned by the contractor and its sub-contractors in equal shares. Failing this, they should agree among themselves on the ownership of IP, for example, by adapting one of the [Lambert Agreements](#). Further details on IP can be found in the agreement between the NC3Rs and the contractor.

Although the NC3Rs is not a joint owner of any IP arising from a project, it is a condition of funding from the NC3Rs that work furthering the 3Rs must be made available to the rest of the bioscience sector. The protection of IP through filing of patents should therefore be pursued without unreasonable delay, and access by third parties to 3Rs benefits must be provided through publication and dissemination, or by appropriate licences, royalty-free or royalty-bearing on fair and reasonable terms. The exact arrangements are detailed in the agreement between the NC3Rs and the contractor.

Sponsors and/or co-funder(s) are also not joint owners of any IP arising from a project. Sponsors benefit from early access to any new technology during the term of the project. Access beyond the project duration can be through granting of royalty-free licences or through favourable pricing for an agreed period.

Any expectations of the Sponsors and/or co-funder(s) in this respect are detailed in the Challenge briefs and included in the contract between the NC3Rs and the Sponsor(s) and/or co-

funder(s). The Sponsor(s) and/or co-funder(s) and the contractor are required to sign a separate agreement detailing the arrangements for access to IP arising from the project and any other matters that are necessary for the project to go ahead.

## 1.7.2 Project management

### **Phase 1 project management**

The contractor is responsible for managing the Phase 1 award and ensuring that sufficient resources are allocated to the study to meet Phase 1 deliverables. They are also responsible for completing the end of **Phase 1 proof-of-concept Report** and **final expenditure statement (FES)** within the agreed timeframe.

### **Phase 2 and Single Phase project management**

The NC3Rs requires the establishment of a Project Management Team whose members include representatives of the contractor, its sub-contractor(s) and the Sponsors. The Chair of the Project Management Team should be the lead representative of the contractor and acts as the liaison with the NC3Rs. The responsibilities of the Chair are described in the agreement between the NC3Rs and the contractor.

The Project Management Team is responsible for ensuring key deliverables are met within agreed timeframes. The Project Management Team should meet quarterly during the award period. The minutes from the Project Management Team meetings are required by the NC3Rs.

Typically, a representative from the NC3Rs will attend the introductory meeting and a minimum of every six (6) monthly Project Management meeting thereafter unless otherwise agreed.

## 1.7.3 Reporting, publication and dissemination

### **Reporting**

All **Phase 1** awardees are required to submit a proof-of-concept report and a final expenditure statement (FES) as part of the Phase 2 application or within four to six (4-6) weeks of the Phase 1 completion/termination date if not applying for Phase 2. Templates for both will be provided as part of the Phase 2 application pack.

All **Phase 2, Single Phase and BGS** awardees are required to submit an end-of challenge report and a FES within three (3) months of the completion/termination date. The end-of challenge report should describe the work undertaken, the achievements and outcomes of the project and details of how the project advanced the 3Rs. The report template, FES and additional guidance will be sent to all awardees four (4) weeks before the completion date.

Failure to provide the requested report and final expenditure statement (FES), within the specified timeframe, may result in funding being rescinded. It is the responsibility of the contractor to manage the funds awarded responsibly and any additional costs incurred above the total amount awarded will not be reimbursed.

### **CRACK IT Advisory Panel meeting**

All CRACK IT Single and Phase 2 contractors will be invited to meet with the CRACK IT Advisory Panel no earlier than six (6) months before and no later than six (6) months after their contract with the NC3Rs expires.

The purpose of the meeting with the CRACK IT Advisory Panel is to update the NC3Rs on progress made in addressing the original Challenge brief and for the Panel to provide tailored advice on next steps, including commercialisation.

The original CRACK IT Challenge Sponsors and the NC3Rs representative on the Project Management Team are encouraged to participate in the meeting with the CRACK IT Advisory Panel.

Table 6: Researchfish reporting requirements

<b>Who</b>	<ul style="list-style-type: none"> <li>▪ Compliance with Researchfish reporting is a requirement for every CRACK IT Contractor.</li> <li>▪ The lead contractor/ BGS awardee is ultimately responsible for ensuring his/her Researchfish record is up-to- date.</li> </ul>
<b>When</b>	<p>Contractors can, and should, submit information to Researchfish all year round and after the contract has ended:</p> <ul style="list-style-type: none"> <li>▪ <b>Phase 1:</b> for at least one (1) year</li> <li>▪ <b>Phase 2:</b> for at least five (5) years</li> <li>▪ <b>Single Phase:</b> for at least three (3) years</li> <li>▪ <b>BGS*:</b> for at least five (5) years</li> </ul> <p>In line with the Research Councils, the NC3Rs also has an <b>annual collection period</b>.</p> <p>There is also a requirement to update Researchfish when <b>your contract is coming to an end</b>.</p>
<b>What</b>	<ul style="list-style-type: none"> <li>▪ Details of all outputs, outcomes and impacts, when available, arising from the contract.</li> <li>▪ In particular, complete the sections on Publications and Replacement, Reduction and Refinement.</li> </ul>
<b>Why</b>	<ul style="list-style-type: none"> <li>▪ Researchfish is one method by which we monitor progress on contracts. Contractors who do not report into Researchfish when requested to do so, or use the system inappropriately, may become ineligible to apply for additional awards from the NC3Rs (and potentially the Research Councils).</li> <li>▪ Researchfish is not a publicly accessible data repository. However, data held in Researchfish may be used by the NC3Rs to populate our website and for production of publications such as our Annual Report.</li> </ul>

\* For BGS reporting purposes: where a BGS award is made, the reporting requirements noted above will supersede those detailed for Single and Phase 2 awards.

### Publication

Alongside the commercialisation and distribution of the Challenge product, award holders are expected to disseminate their results by publishing in appropriate scientific journals and at relevant conferences. The [Research Council UK policy](#) on open access should be adopted. Award holders are required to report research outputs and outcomes on a regular basis using [Researchfish](#). There is a mandatory annual collection period for the submission of data.

Publications should have the prior agreement of the Project Management Team and in particular publication timing, must respect the need to protect IP arising from the work.

The NC3Rs support for the project should be acknowledged on all publications and presentations where such support has been significant. The NC3Rs should be informed of any publications or other promotional material or events arising from the award.

Studies using animals should be reported in accordance with the [ARRIVE guidelines](#) taking into account the specific editorial policies of the journal concerned.

Sponsors are permitted to place organisational logos on promotional materials arising from the collaboration by prior agreement with the NC3Rs.

## Section 2: Business Growth Scheme

### 2.1 Overview

The NC3Rs has introduced a Business Growth Scheme (BGS); where CRACK IT Challenge contractors can apply for additional support, of up to £50k (inclusive of VAT/EU reverse charges) for 12 months, to maximise their business strategy for near-market ready products and services.

**The BGS has been designed to support the business and commercial opportunities that arise from technology developed during the Challenge. These funds will not be awarded to support further R&D work that was not completed in the Challenge period.**

This document provides a comprehensive guide to participants applying to the BGS. All awards made under the BGS constitute *de minimis* aid.

Table 7: Business Growth Scheme overview

<b>Scheme</b>
<p>The Business Growth Scheme (BGS) has been designed to support the business and commercial opportunities that arise from technology developed from CRACK IT Challenges.</p> <p>CRACK IT Challenge contractors can apply for additional support of up to £50k (inclusive of VAT/EU reverse charges) for 12 months. Awarded funds will not support R&amp;D non-completed during the Challenge period.</p>
<b>Eligibility</b>
<ul style="list-style-type: none"> <li>▪ Open to any CRACK IT Single Phase or Phase 2 contractor (includes sub-contractors).</li> <li>▪ Applicants must be European Union (EU)-based and from an established commercial entity.</li> <li>▪ Only one application to the BGS, per Challenge, will be accepted.</li> <li>▪ BGS awards constitute <i>de minimis</i> aid. Any one organisation cannot be provided with more than the <i>de minimis</i> funding threshold of €200k over a three year fiscal period.</li> </ul>
<b>Application and review process</b>
<p>Applications to the BGS:</p> <ul style="list-style-type: none"> <li>▪ Will only be accepted following the end of Challenge presentation to the CRACK IT Advisory Panel (CAP).</li> <li>▪ Will be within one (1) year of completion of the Challenge contract.</li> <li>▪ Must be made using the application form provided.</li> <li>▪ Will be reviewed by the CAP within six (6) weeks of the NC3Rs receiving the application.</li> </ul>
<b>Agreements and awards</b>
<p>Prior to award, the successful applicant's organisation signs an agreement with the NC3Rs. Up to two (2) awards will be made each financial year.</p> <p>The lead applicants are informed by email of the decision of the CAP approximately one (1) week after the Panel meeting.</p>
<b>Post-award</b>
<p>The lead contractor will be responsible for ensuring key deliverables of the BGS plan are met within agreed timeframes.</p> <p>All BGS awardees are required to submit a <b>final report</b> and a <b>final expenditure statement (FES)</b> within three (3) months of the completion/termination date.</p>

## 2.2 Eligibility criteria and scheme remit

- The BGS is open to any **CRACK IT Single Phase or Phase 2 contractor**, including sub-contractors that were part of the original winning *consortium*, who have approval to apply from their CRACK IT Challenge Project Management Team.<sup>4</sup>
- All CRACK IT Challenge contractors will be invited to present their Challenge outcome to the CRACK IT Advisory Panel (CAP) within the period of six (6) months before and six (6) months after their contract with NC3Rs expires. Contractors wishing to apply to the BGS will have an opportunity to outline their proposal as part of the presentation.
- The CAP will provide feedback on the proposed use of the BGS and recommend whether an application should be invited.
- An application form will be provided by the CRACKIT team who will advise on deadlines for submission and decision dates.
- Applicants must be European Union (EU)-based and from an established commercial entity at the time of submitting an application.
- Only **one** application to the BGS, per Challenge, will be accepted.
- Under European Commission Regulation 1407/2013 (*De Minimis* Regulation), BGS awards constitute *de minimis* aid. There is a ceiling of €200,000 for all *de minimis* aid provided to any one organisation over a three (3) year fiscal period (i.e. current April to March and previous two financial years). Any *de minimis* aid awarded under BGS will be relevant if applicants wish to apply, or have applied, for any other *de minimis* funding.

Further information on State Aid can be found in the [State Aid Manual](#).

### **Scheme remit**

BGS applications are expected to address the commercialisation of a technology/ product that, through the CRACK IT Challenge competition, has already completed the majority of R&D work required to produce a market-ready product. Using the modified technology readiness levels (mTRL) defined by Phadke & Vyakarnam<sup>5</sup> as guidance, a mTRL level of 3-6 is expected to be the minimum starting point for applying to the scheme. The aim of the scheme is to support activities towards mTRL 7-9 (Table 8).

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<sup>4</sup> A Project Management Team consisting of representatives from the contractors, sub-contractors, Sponsors and NC3Rs is established for each funded CRACK IT Challenge. The Project Management Team is responsible for ensuring key deliverables are met within agreed timeframes during the CRACK IT Challenge.

<sup>5</sup> Taken from Phadke & Vyakarnam, *Camels, Tigers and Unicorns: Rethinking Science and Technology-enabled Innovation*, World Scientific Publications, 2017

Table 8: Modified Technology Readiness Levels (mTRL) and their definitions

<b>mTRL 0</b>	<b>Research in progress</b> Fundamental research activity before any potentially useful and validated science or technology has been established
<b>mTRL 1</b>	<b>Validated research: Start concept definition</b> At the point at which the conceptual application of the technology has been defined in outline terms
<b>mTRL 2</b>	<b>Initial concept defined</b> The conceptual application has now been converted to a definition of the product or service which can potentially be offered using the technology
<b>mTRL 3</b>	<b>Working prototype or demonstrator</b> A working prototype or demonstrator has been built
<b>mTRL 4</b>	<b>Product or service testing and concept refinement</b> The new product, service or technology has been refined/modified following feedback from the initial customer
<b>mTRL 5</b>	<b>Proven product or service</b> The product or service is ready at a functional level, without the collateral around the product including the method of deployment and the proposed business model
<b>mTRL 6</b>	<b>Deployment with early customers in real commercial environment</b> The product or service is now ready for use with early Customers, and so includes all the associated collateral, including a service infrastructure where relevant.
<b>mTRL 7</b>	<b>Product or service ready for testing in real user environment</b> Early customer feedback has been used to define the modified product or service functionality, its required performance and critically, the chosen business model.
<b>mTRL 8</b>	<b>Techno-commercial refinement of product or service</b> The refined product or service is now ready for deployment with mainstream customers.
<b>mTRL 9</b>	<b>Ready for commercial deployment with real customers</b> The final product or service is now ready for commercial launch, including go-to-market collateral and proven business model. The challenge now is growing the mainstream customer base.

The remit of the BGS includes:

- Validating the core technology to increase customer confidence (mTRL7).
- Building a portfolio of clients and prospective clients (mTRL7 and 8).
- Establishing confidence (scientifically and commercially) to operate in the market (mTRL7 and 8).
- Delivering a product scaled to a level appropriate for commercial activities and attracting investment capital, where appropriate (mTRL 9).

Activities within scope may include but are not limited to:

- **Validation for customer confidence:** Specific testing of a small set of potential customer/sector defined compounds to build customer confidence. (mTRL7, 8).
- **Consultancy:** For example, advice on business/commercialisation strategy, business development, pitching for investment and market analysis (mTRL 8,9).
- **Marketing:** Communications to attract potential investors and customers including website design, travel, academic publications, conference and exhibition fees (mTRL 8,9).
- **Demonstrators:** For example, production and installation of demonstrators at one or more sites to generate new client interest and provide access for trial use. Costing of equipment to be used primarily for this purpose is also within scope (mTRL 7,8).
- **Manufacture:** For activities including design for manufacturability, manufacture, miniaturisation, manufacturing efficiencies and investigating and implementing a supply chain for product generation. Costing of equipment to be used primarily for this purpose is also within scope (mTRL 8,9).

#### Activities not in scope for the BGS include:

- Research and development as a core activity.
- Validation and/ or other activities that were included in the original CRACK IT Challenge project plan.
- Merchandising and advertising activities and materials.
- Export activities.

## 2.3 How to apply

Applications for the BGS will only be accepted following the end of Challenge presentation to the CAP. Contractors wishing to be considered for the BGS will have the opportunity to pitch to the CAP either at the same time as their end of Challenge presentation or at a separate occasion within one (1) year of completion of the Challenge contract. Following the CAP presentation, the Panel will provide feedback on the proposed use of the BGS and recommend whether an application should be invited.

Applicants are expected, before submitting an application, to have discussed their proposal with their own organisation or any other body whose co-operation will be required in the conduct of the project, including sub-contractors and their **Project Management Team**. By submitting an application, applicants are confirming that the information provided in the application is complete and true, that they are actively engaged in the project and will be responsible for its overall management, and that they agree to administer the award if made.

### General Guidance

Applications for the BGS must be made using the application form provided. Guidance on completion of the application form can be found in [Section 2.4](#). Completed applications must be sent by email to [crackitenquiries@nc3rs.org.uk](mailto:crackitenquiries@nc3rs.org.uk). All applications are treated in confidence.

- Application forms and attachments must be submitted as **PDF files**.
- Failure to complete mandatory fields on the application form and to submit all required attachments may result in the return of the application without review.

- The application form should be completed using a font size no smaller than 10pt (Arial) and text limits must not be exceeded.
- The use of acronyms should be kept to a minimum.

### Attachments

Supporting information can be provided in the form of attachments as indicated within this guidance and the application form. Attachments must:

- Be submitted as separate **PDF files** and not added or pasted within the application form.
- Be named appropriately and indicate the application form section number to which they refer e.g. 'Section 6 – Additional pictures/diagrams'.
- Be completed using a font size no smaller than 10pt (Arial).

Only provide attachments as specified in the application form and in this guidance. Any additional materials or documentation submitted will not be considered and may result in your application being rejected or returned.

Questions about the application process should be addressed directly to your NC3Rs Representative or via email [crackitinqueries@nc3rs.org.uk](mailto:crackitinqueries@nc3rs.org.uk) or call +44 (0)20 7611 2233.

## 2.4 BGS application form

This section contains guidance on how to complete the BGS application form. Sub-sections are numbered as they appear in the application form.

### 1. Application

**Project title:** Please provide your own title for the project. This should be both clearly descriptive and concise. It should contain keywords relevant to the project.

**Project duration:** Applicants can request up to the maximum duration of 12 months, as specified in the BGS brief.

**Proposed start date:** Please specify the date upon which BGS activities will commence. This must be within eight (8) weeks of confirmation of the award.

**Total project cost:** Applicants can request up to the maximum total cost, (inclusive of VAT/EU reverse charges) of £50k. Requests for more than this sum will be rejected.

For applications from organisations based outside of the United Kingdom, please note that a European Union (EU) reverse charge of VAT will be applied to your award. This will be charged at 20% and will need to be taken into consideration when costing your application, as the maximum amount that will be paid out, inclusive of VAT and EU Reverse Charges, will not exceed the total amount of £50k.

### 2. Details of Lead Applicant Organisation

Please include the name of the company applying to the BGS, registered address, company and VAT registration numbers and other details as requested on the application form. Applicants must be a registered commercial entity and based within the European Union.

### 3. Details of Lead Contact in Organisation

Please include the name of the lead contact in the company applying to the BGS, position in the company and contact details.

4. Original CRACK IT Challenge awarded:

**CRACK IT Challenge number and title:** Please provide the number and title of the CRACK IT Challenge.

**CRACK IT Challenge funding received:** Please detail the amount of funding received for the CRACK IT Challenge award from the NC3Rs.

**CRACK IT Challenge start date:** Date on which the CRACK IT Challenge commenced.

**CRACK IT Challenge completion date:** Date on which the CRACK IT Challenge completed or if still in progress, the date on which the CRACK IT Challenge is due to complete.

Provide details of the CRACK IT Challenge lead applicant organisation and lead contact, if different from that stated in Section 2 and 3.

5. Commercial opportunity

**Market opportunity:** Please describe the unmet need, size of the market opportunity and potential customers for the technology/product. The maximum word limit for this section is 300 words.

**Competition:** Please describe competing technologies/products and the competitive advantage of your approach. The maximum word limit for this section is 200 words.

**Intellectual property:** Please provide details of any existing patents or other forms of intellectual property (i.e. know how, trademark) that have arisen from the original CRACK IT Challenge. In addition, please indicate any anticipated IP, which may arise in the process of commercialising the technology/product and how this would be handled i.e. the proposed arrangements for ownership. Please provide details of any freedom to operate searches conducted to date (or plans for the future) and any restrictions this may impose on the dissemination and exploitation of the technology/product. The maximum word limit for this section is 200 words.

**Associated attachment (optional):** Summary of patent filings.

**Business model:** Please describe the business model and route to commercialisation of the technology/product. Please include the barriers and key risks to commercialisation and how you plan to address them. Please also describe any interactions with potential customers and/or investors, together with any feedback received. The maximum word limit for this section is 300 words.

**Associated attachment (optional):** Letters of support/intent from potential customers.

6. Use of BGS funds

Please explain in detail the proposed use of BGS funds, including milestones, timelines and costs. Describe how BGS funding will de-risk your commercialisation strategy and how this aligns with the goals of the BGS scheme as set out in the BGS guidelines document **and** Modified Technology Readiness Levels (mTRLs). Please outline your future plans (milestones, timelines, costs and longer term financing plans) following successful completion of your BGS proposal. Activities included as part of the original Challenge project, but which were not completed, are not eligible for BGS funding. The maximum word limit for this section is 600 words.

**Please note:** If a proposal includes animal work, the '[Justification of animal use/ experimental design form](#)' must be completed and included as part of the application. Further guidance can be found in [Section 1.4.1](#).

**Associated attachment (optional):** Additional milestones/Gantt chart (maximum two sides of A4).

## 7. Team and Expertise

Please provide a detailed description of the current team (skills, expertise and track record). Identify any gaps in your team/experience where additional support is anticipated in the future. Relevant commercial and management expertise must also be included. The maximum word limit for this section is 600 words.

**Associated attachment (compulsory):** The CVs of up to five (5) principal team members may be combined and included as a separate attachment (maximum one (1) side of A4 per team member).

## 8. Application Finances

BGS contracts are non-Full Economic Costing (FEC) and as such, applicants can apply for **100% directly incurred costs**. Please provide a summary of the overall costs for the whole project, inclusive of VAT/EU Reverse Charges, as appropriate<sup>6</sup>.

For applications from organisations based outside of the United Kingdom, please note that a European Union (EU) reverse charge of VAT will be applied to your award. This will be charged at 20% and will need to be taken into consideration when costing your application, as the maximum amount that will be paid out, inclusive of VAT and EU Reverse Charges, will not exceed the total amount of £50k.

### Direct Costs

These are costs that are specific to the project, including:

- Labour costs for all those contributing to the project broken down by individual
- Material costs (including consumables specific to the project)
- Equipment costs
- Animal costs\*
- Travel and subsistence costs
- Other costs specifically attributed to the project

\*Where applications involve the use of animals, applicants are expected to provide justification for this – see [Section 1.4.1](#) for further information.

Itemisation of costs and methods of calculation may be requested to support the application at a later date.

In addition, please provide justification for the resources required to undertake the proposed project.

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<sup>6</sup> It is the responsibility of the lead applicant to determine whether VAT/EU RC should be paid; if VAT/EU RC should be paid, the total amount, including VAT/EU RC, will not exceed the total amount of £50k.

**Additional funding from external sources:** Please provide details of additional funding from external sources that will support this project.

**De minimis aid:** Please advise of any other *de minimis* aid which your commercial entity, and any entity linked to it, has received during the last three (3) fiscal years (April – March). Please include any additional funding described in the 'Additional funding from external sources' table above which is subject to *de minimis* aid rules. Note that *de minimis* aid includes not only the grant but also assistance such as free or subsidised consultancy services, marketing advice etc. If you are in any doubt about whether previous assistance received falls under *de minimis* assistance, please include it.

## 9. Declaration

The BGS applicant is expected to have discussed and sought approval of the application with their own organisation and with any other body whose co-operation will be required to deliver the project, including the CRACK IT Challenge Project Management Team. The applicant will need to obtain consent from an authorised officer or appropriate signatory who will sign the agreement if successful. The agreement is a legally binding document and subject to the outcome of this competition. By submitting the application, you are confirming that the information given, in this application, is complete and that you are actively engaged in this project and responsible for its overall management and agree to administer the award if made. You are also confirming that you have read and understood the relevant explanatory materials including this Guide for Participants.

Table 9: Summary of attachments

Application form section	Attachment name	Page limit (sides of A4)
Section 5.3	Summary of patents	Template provided in application form
Section 5.4	Letters of support	1 per letter
Section 6	Additional milestones/ Gantt chart	2
Section 7	CVs (up to five)	1 per team member (5 in total)

### 2.4.1 Animal use and experimental design

Where a proposal includes animal work, the '[Justification of Animal Use/Experimental Design form](#)', must be completed and included as part of the application. Guidance on completing this form can be found within [Section 1.4.1](#).

## 2.5 Assessment procedure

Once received, applications to the BGS will be reviewed by the [CRACK IT Advisory Panel](#) within six (6) weeks of the NC3Rs receiving the application. Awards will be made to successful applicants, subject to them signing a non-negotiable agreement with the NC3Rs. Up to two awards can be made each financial year.

The lead applicants are informed by email of the decision of the CRACK IT Advisory Panel approximately one week after the Panel meeting.

The CRACK IT Advisory Panel's decision is final and is not open to appeal.

Table 9: CRACK IT Advisory Panel scoring criteria

Assessment Criteria
<ul style="list-style-type: none"><li>▪ Potential for BGS funding to progress technology to mTRLs 7-9 (as defined in <a href="#">Table 7</a>)</li><li>▪ Scale of the market opportunity</li><li>▪ Value for money and justification for use of funds in achieving deliverables</li><li>▪ Expertise and track record of the team</li><li>▪ Eligibility of funding within the <i>de minimis</i> aid criteria</li><li>▪ Ability to secure independent funding</li></ul>

Membership of the Advisory Panel is published on the NC3Rs Innovation Platform. All panel members sign a confidentiality agreement upon appointment and are expected to abide by the principles set out in the [Code of Practice for members of Council and MRC boards](#).

Members also complete a Declaration of Interest form which is also published on the [NC3Rs Innovation Platform](#).

## 2.6 Award process

The NC3Rs leads the awards' announcements via the [NC3Rs Innovation Platform](#). Award holders may be required to participate in media-related activities regarding the announcements.

BGS awards are made to the lead applicant's organisation which then administers the award and subsequent process requirements including returning signed documentation.

For successful applications, involving more than one organisation, the lead applicant (contractor) must agree to manage the award from the NC3Rs on behalf of the others (the sub-contractors). Sub-contractors negotiate their agreements with the contractor directly.

Applicants must be able to demonstrate that, should they be successful in their application, they have a team in place ready to start working on the project on receipt of the agreement.

Contracts are expected to be finalised and signed **within two weeks** of receipt.

BGS awards are made to the successful applicants subject to them signing a non-negotiable agreement with the NC3Rs. BGS work should commence promptly and within eight (8) weeks of

the confirmation of the award from the NC3Rs. Failure to comply will result in the award being terminated.

To ensure rapid commencement of the work, all funding will be provided upfront.

### **Important information**

The Terms and Conditions for BGS awards are set out in the agreement between the NC3Rs and the successful applicant (BGS contractor Agreement).

Agreements:

- Agreements between the NC3Rs and the successful applicants take the form of standard contract research agreements from the NC3Rs.
- These agreements are intended to protect and benefit both the NC3Rs and the Challenge winners to ensure the effective delivery of the research.
- BGS agreements are standard and the NC3Rs will not make changes to them.

## **2.7 Post award information**

### **2.7.1 Intellectual property**

Intellectual property (IP) developed within the project is the property of the contractor (successful BGS applicant) and its sub-contractors, as described in the agreement between the NC3Rs and the contractor. One recipient of NC3Rs funding should be nominated as the IP manager for the project. The NC3Rs does not provide a model agreement but suggests as a default that IP arising from the project should be jointly owned by the contractor and its sub-contractors in equal shares. Failing this, they should agree among themselves on the ownership of IP, for example, by adapting one of the [Lambert Agreements](#). Further details on IP can be found in the agreement between the NC3Rs and the contractor.

Although the NC3Rs is not a joint owner of any IP arising from a project, it is a condition of funding from the NC3Rs that work furthering the 3Rs must be made available to the rest of the bioscience sector. The protection of IP through filing of patents should therefore be pursued without unreasonable delay, and access by third parties to 3Rs benefits must be provided through publication and dissemination, or by appropriate licences, royalty-free or royalty-bearing on fair and reasonable terms. The exact arrangements are detailed in the agreement between the NC3Rs and the contractor.

### **2.7.2 Project management**

The lead contractor will be responsible for ensuring key deliverables of the BGS plan are met within agreed timeframes and will liaise with the NC3Rs to provide an update on progress at quarterly intervals unless otherwise agreed.

### **2.7.3 Reporting**

All BGS awardees are required to submit a **final report** and a **final expenditure statement (FES)** within three (3) months of the completion/termination date. The final report should describe the work undertaken, the achievements and outcomes of the project and details of how the project advanced the 3Rs. The report template, FES and additional guidance will be sent to all awardees four (4) weeks before the completion date.

Failure to provide the requested report and FES, within the specified timeframe, may result in funding being rescinded. It is the responsibility of the contractor to manage the funds awarded responsibly and any additional costs incurred above the total amount awarded will not be reimbursed.

## **Researchfish and publications**

Award holders are expected to disseminate their results by publishing in appropriate scientific journals and at relevant conferences. The [Research Council UK policy](#) on open access should be adopted. Award holders are required to report research outputs and outcomes on a regular basis using [Researchfish](#). There is a mandatory annual collection period for the submission of data.

The NC3Rs support for the project should be acknowledged on all publications and presentations where such support has been significant. The NC3Rs should be informed of any publications or other promotional material or events arising from the award.

It is the responsibility of the contractors to keep the NC3Rs informed in a timely manner of outputs from the BGS-funded project.

Studies using animals should be reported in accordance with the [ARRIVE guidelines](#) taking into account the specific editorial policies of the journal concerned.

Further information on [Researchfish](#) reporting requirements can be found in [Table 6](#).